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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=746B029CD80E437D9F62708C339A9EC8-GIFT, JEFF]

**Sent**: 1/28/2011 3:20:58 PM

To: Jane Caldwell [Caldwell.JaneLNDU@usepa.onmicrosoft.com]

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Subject: Re: RI in the news

Attachments: DIB0001

## **Deliberative Process / Ex. 5**

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From: Jane Caldwell/DC/USEPA/US

To: Jeff Gift/RTP/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Danielle

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Date: 01/28/2011 09:48 AM

Subject: RI in the news

Dear All,

## **Deliberative Process / Ex. 5**

Jane Caldwell

News Headline: CITING DATA DISPARITY, INDUSTRY RENEWS CALL FOR EPA TO DROP METHANOL STUDY  $|\boxtimes|$ 

Outlet Full Name: Inside EPA Weekly Report

**News OCR Text:** Industry officials are renewing their call for EPA to remove from its website a draft estimate of the risks posed by methanol citing a new industry-funded report that shows federal scientists found a significantly smaller cancer incidence than Italian researchers whose work the agency relied upon in the risk assessment.

The Methanol Institute sent the report to EPA earlier this month, along with its renewed request filed under the Data Quality Act that the agency pull from its website its draft assessment of methanol's toxicity.

The industry report, compiled using data it acquired under the Freedom of Information Act, provides new ammunition to the group's effort under the Data Quality Act to push back against one of six risk assessments that EPA is reassessing because they relied on studies from the controversial Italian laboratory known as the Ramazzini Institute

Several industry associations have also filed a separate petition to EPA Administrator Lisa Jackson, urging her to obtain a full pathology working group review of the Ramazzini studies included in the IRIS assessments or publicly decline to use them in the final assessments.

EPA's draft methanol assessment, released last January, for the first time identifies methanol as a likely human carcinogen, and also sets a first-time safe daily dose for inhalation exposure, or reference concentration (RfC), of 2 milligrams per cubic meter of air.

The assessment was one of six that EPA announced last June it was pulling for review because they referenced studies from the Ramazzini Institute.

EPA halted progress on four ongoing draft assessments containing Ramazzini data -- including those of methanol, the fuel additives methyl tertiary butyl ether (MTBE) and ethyl tert-butyl ether (ETBE), and the plastic ingredient acrylonitrile -- as well as existing assessments of vinyl chloride and 1,1 dichloroethylene (DCE), which were published on the IRIS website in 2000 and 2002 respectively.

EPA's decision followed the release of a report from the National Toxicology Program (NTP), indicating that its pathologists had come to different conclusions that Ramazzini pathologists on how many of the lab rats in its methanol study developed cancerous tumors (Inside EPA, June 18).

Now the Methanol Institute's consultant, George Cruzan, has written a report based on data obtained from NTP under FOIA that details the extent of the disparity between Ramazzini's cancer conclusions and those of the NTP pathologists who reviewed some of the methanol study slides. Cruzan found that NTP pathologists found significantly fewer cancer incidence among lab rats than what Ramazzini scientists found. For example, "NTP pathologists did not agree with the [Ramazzini] pathologist on most lymphomas and ear cancers," Cruzan writes.

Cruzan indicates Ramazzini scientists reported a total of 52 lab rats with lympho-immunoblastic lymphoma in their lungs and other tissues, while the NTP pathologists considered only 13 of these rats' tissues represented lymphomas. Relevant documents are available on InsideEPA.com.

Cruzan's report provides additional evidence that the Methanol Institute references in its Jan. 7 letter to EPA, pressing agency staff for a decision on the industry association's request to pull the draft methanol assessment from its website. The group argues that EPA indicated in October correspondence that it would respond within 90 days, yet the agency has not done so.

"The new data from NTP are quite revealing as they further accentuate the diverging opinions between U.S. government pathologists and those at the Ramazzini Foundation regarding the potential impact of exposure to methanol," the Methanol Institute's Greg Dolan writes in the January letter. "The information provided by the NTP also makes it clear that the Ramazzini Foundation data are not scientifically reliable."

Dolan points to Cruzan's conclusions: NTP pathologists disagreed with Ramazzini pathologists regarding most of the Italians' lymphoma findings, and that "The NTP analysis of the RF slides does not support a conclusion of increased cancers from methanol exposure."

Cruzan's report explains that "The total number of control rats with leukemias, lymphomas or histiocytic sarcomas in the lung and other tissues was 13 of 100 [control rats versus] 9 of 100 in the high-dose rats. . . None of the incidences in the high-dose males were significantly different from the controls (p>0.05 by Fisher's exact test). Therefore, none of the cancers that the [Ramazzini] publication reported as increased was reported as increased by NTP." -- Maria Hegstad

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